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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/932,227	09/17/1997	ERIC T. FOSSEL		5092

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EXAMINER
MULLIS, JEFFREY C

ART UNIT	PAPER NUMBER
1711	23

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

AS-23

Office Action Summary	Application No. 08/932,227	Applicant(s) FOSSEL, ERIC T.	
	Examiner Jeffrey C. Mullis	Art Unit 1711	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35,38-44,47-53,56-59 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35,38-44,47-53,56-59,61- 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

This Office action is in response to applicant's CPA request of 12-19-01.

Claims 33-35, 38-44, 47-53, 56-59 and 61-63 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not disclose L-arginine and L-arginine with concentrations broadly of 0.25-25% by weight or ionic salt concentrations of 0.25-25% by weight but at most only discloses such concentrations for specific compositions. Again applicant's concentration ranges are therefore new matter.

Claims 33-35, 38-44, 47-53,56-59 and 60-63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's statements regarding the concentrations of the instant claims are contradictory given that applicant at the bottom of page 4 of his remarks where applicant argues that the "concentrations needed to provide an effective treatment" have been "introduced into the amended claims". However the concentrations referred to in applicant's Declaration, namely 0.25-25% by weight differ from the concentrations argued by

applicant in applicant's Declaration. Note in this regard that applicant argues that the 4.9 grams per liter concentration of L-arginine is insufficient despite the fact that the lower limit for arginine recited in the claims is 0.25% which is lower than 0.49%. Likewise the concentrations of ionic salt argued to be insufficient in Weuffen are actually higher than the lower limit of salt recited by the claims. The same situation exists for Hechtman are higher than the lower limit recited in the instant claims.

The Declaration under 37 CFR 1.132 filed 12-19-01 is insufficient to overcome the rejection of claims 33-34, 38, 51-53 and 59 based upon either Weuffen et al. or Hechtman as set forth in the last Office action because: Applicant argues that the concentrations of the instant claims are not suggested by Weuffen et al. or Hechtman. However for the reasons set out in the above rejection under 35 U.S.C. § 112 second paragraph, it is unclear whether the instant claims actually embrace concentrations recited by the prior art. It appears that the specific numerical concentrations recited by the instant claims are taught by the patents and applicant appears to imply that the numerical concentrations are actually those that are being claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-34, 38, 51-53 and 59 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weuffen et al. (USP 5,629,002).

See the Office action of Paper No. 6 at page 4 line 5 et seq.

Claim 33 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hechtman (USP 5,595,753).

See the Office action of Paper No. 6 at the paragraph bridging pages 4 and 5 et seq.

Claims 61-63 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Garfield et al. in view of Hechtman, Altadonna (USP 5,853,768), Cooke et al. (USP 5,428,070), Saavedra et al. (USP 5,632,981) and Cooper et al.

See the Office action of Paper No. 8 at the paragraph bridging pages 3 and 4 et seq.

Applicant's arguments filed 12-19-01 have been fully considered but they are not deemed to be persuasive.

Applicant's arguments regarding the allegation that patentees' concentrations and those of applicant are different have been dealt with above in the response to the Declaration.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

J. Mullis:cdc

March 21, 2002